

Applicant Initiated Interview Request Form

Application No.: 09/642,205 First Named Applicant: M. P. Neeper
 Examiner: Q. Janice Li Art Unit: 1632 Status of Application: pending

Tentative Participants:

(1) Alysia A. Finnegan (2) Joanne M. Giesser
 (3) Q. Janice Li (PTO) (4) _____

Proposed Date of Interview: 6/24/2003 Proposed Time: 2:00 (~~AM~~/PM)

Type of Interview Requested:

(1) ☒ Telephonic (2) ☐ Personal (3) ☐ Video Conference

Exhibit To Be Shown or Demonstrated: ☐ YES ☒ NO

If yes, provide brief description: _____

Issues To Be Discussed

Issues (Rej., Obj., etc)	Claims/ Fig. #s	Prior Art	Discussed	Agreed	Not Agreed
(1) <u>Rej.</u>	<u>24-29</u>	<u>N/A</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(2) <u>Rej.</u>	<u>1-4, 6, 9, 10,</u> <u>13, 14, 17, 19,</u>	<u>N/A</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(3) _____	<u>20, 24-30</u>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(4) _____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Continuation Sheet Attached

Brief Description of Arguments to be Presented:

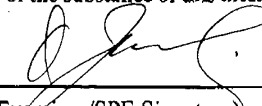
Applicants propose new amendments (attached) to place application in condition for allowance. In the alternative, Applicants request removal of finality pursuant to MPEP §706.07 because new §112 para. 1 rejection of claims 24-29 (alleged non-enablement of mode of administration.)
An interview was conducted on the above-identified application on _____.

NOTE:


This form should be completed by applicant and submitted to the examiner in advance of the interview (see MPEP §713.01).

This application will not be delayed from issue because of applicant's failure to submit a written record of this interview. Therefore, applicant is advised to file a statement of the substance of this interview (37 CFR 1.133(b)) as soon as possible.


 (Applicant/Applicant's Representative Signature)


 (Examiner/SPE Signature)

This collection of information is required by 37 CFR 1.133. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 21 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Received from <732 594 2250> at 6/19/03 10:50:23 AM [Eastern Daylight Time]  the form, call 1-800-PTO-9199 and select option 2.



Merck & Co., Inc.
P.O. Box 2000
Rahway, NJ 07065
Patent Department

Facsimile Cover Sheet

TODAY'S DATE: June 19, 2003

PLEASE DELIVER THE FOLLOWING MATERIALS TO:

Examiners Name: Q. Janice Li
Examiner's Fax Number: 703-746-5158
Group Number: 1632

THIS MESSAGE IS FROM:

Name: Alysia A. Finnegan Phone Number: (732) 594-2583
Mail Location: RY 60-30 Fax Number: (732) 594-4720

RE:

U.S. Appl. Serial No.: 09/642,205
Filing Date: August 21, 2000
Applicants File Ref: 20413Y
For: SYNTHETIC HUMAN PAPILLOMAVIRUS GENES

NUMBER OF PAGES BEING TRANSMITTED (INCLUDING COVER): 7

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June 19, 2003
Date

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Proposed Amendments to Claims

1. (Twice Amended) A synthetic polynucleotide comprising a sequence encoding a codon-optimized human papillomavirus serotype 16 (HPV16) protein[, or mutated form thereof which has reduced protein function for viral replication and cellular transformation as compared to wild-type protein, but which maintains immunogenicity,] wherein said polynucleotide sequence comprises codons that are optimized for expression in a human host.

2. A polynucleotide according to Claim 1 wherein the protein is selected from the group consisting of: L1, L2, E1, E2, E4, E5, E6 and E7.

3. A polynucleotide according to Claim 2 wherein the protein is selected from the group consisting of: L1, E1, E2, and E7.

4. A polynucleotide according to Claim 2 which is DNA.

6. (Previously Amended) A polynucleotide according to Claim 4 wherein the protein is an HPV16 L1 protein.

7. A polynucleotide according to Claim 6 which comprises the polynucleotide of FIGURE 1 (SEQ.ID.NO: 1).

[9. A polynucleotide according to Claim 4 wherein the protein is a mutated form of E1.]

10. (Previously Amended) A polynucleotide according to Claim [9] 4 which is an HPV16 E1 protein.

11. (Amended) A synthetic polynucleotide [according to Claim 10] which comprises a sequence of nucleotides as set forth in [the polynucleotide of] FIGURE 2 (SEQ. ID.NO:2).

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[13. A polynucleotide according to Claim 4 wherein the protein is a mutated E2 protein.]

[14. A polynucleotide according to Claim 13 which is an HPV16 E2 mutated protein.]

15. (Amended) A synthetic polynucleotide [according to Claim 14] which comprises a sequence of nucleotides as set forth in [the polynucleotide of] FIGURE 3 (SEQ. ID.NO: 3).

17. (Previously Amended) A polynucleotide according to Claim 4 wherein the protein is an HPV16E7 protein.

18. (Amended) A synthetic polynucleotide [according to Claim 17] which comprises a sequence of nucleotides as set forth in [the polynucleotide of] FIGURE 4 (SEQ. ID.NO:4).

19. (Twice Amended) An adenoviral vaccine vector comprising an adenoviral genome with a deletion in the E1 region, and an insert in the E1 region, wherein the insert comprises an expression cassette comprising:

A) a polynucleotide encoding a codon-optimized HPV16 protein selected from the group consisting of L1, E1, E2, and E7 proteins [or mutant forms thereof], wherein said polynucleotide is codon-optimized for expression in a human host cell; and

B) a promoter operably linked to the polynucleotide.

20. A vector according to Claim 19 wherein the adenoviral genome also contains a deleted E3 region.

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21. (Previously Amended) A shuttle plasmid vector comprising a plasmid portion and an adenoviral portion, the adenoviral portion comprising: an adenoviral genome with a deletion in the E1 region, and an insert in the E1 region, wherein the insert comprises an expression cassette comprising:

A) a polynucleotide encoding a codon-optimized HPV16 protein selected from the group consisting of L1, E1, E2, and E7 proteins, wherein said polynucleotide is codon-optimized for expression in a human host cell; and

B) a promoter operably linked to the polynucleotide.

22. (Previously Amended) A vaccine plasmid comprising a plasmid portion and an expression cassette portion, the expression cassette portion comprising:

A) a polynucleotide encoding a codon-optimized HPV16 protein selected from the group consisting of L1, E1, E2, and E7 proteins, wherein said polynucleotide is codon-optimized for expression in a human host cell; and

B) a promoter operably linked to the polynucleotide.

23. (Previously Amended) A plasmid according to Claim 22 wherein the plasmid portion is V1Jns.

24. (Twice Amended) A method for inducing immune responses to HPV16 in a human subject [vertebrate] which comprises administering to [a vertebrate] the subject between 1 ng and 100 mg of the composition of Claim 1 [to the vertebrate].

25. (Twice Amended) A method for inducing immune responses to HPV16 in a human subject [vertebrate] which comprises administering to [a vertebrate] the subject between 10^{11} - 10^{12} particles of an adenoviral vector carrying the composition of Claim 1 [to the vertebrate].

26. (Twice Amended) A method for inducing an immune response against human papillomavirus type 16 (HPV16) in a human subject [vertebrate], comprising

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A) administering to [a vertebrate] the subject a first vector comprising a polynucleotide encoding a codon-optimized HPV16 protein selected from the group consisting of L1, E1, E2, and E7 proteins, wherein said polynucleotide is codon-optimized for expression in a human host cell;

B) allowing a predetermined amount of time to pass; and

C) administering to said [vertebrate] subject a second vector comprising adenoviral vaccine vector comprising an adenoviral genome with a deletion in the E1 region, and an insert in the E1 region, wherein the insert comprises an expression cassette comprises

i) a polynucleotide encoding a codon-optimized HPV16 protein selected from the group consisting of L1, E1, E2, and E7 proteins [or mutant forms thereof], wherein said polynucleotide is codon-optimized for expression in a human host cell; and

ii) a promoter operably linked to the polynucleotide.

[27. A method according to Claim 26 wherein the vertebrate is human.]

28. (Twice Amended) A method for inducing immune responses to HPV16 in a human subject [vertebrate] comprising

A) administering to [a vertebrate] the subject a plasmid vaccine, wherein the plasmid vaccine comprises a plasmid portion and an expression cassette portion, the expression cassette portion comprising:

i) a polynucleotide encoding a codon-optimized HPV16 protein selected from the group consisting of L1, E1, E2, and E7 proteins, wherein said polynucleotide is codon-optimized for expression in a human host cell; and

ii) a promoter operably linked to the polynucleotide;

B) allowing a predetermined amount of time to pass; and

C) administering to said [vertebrate] subject an adenoviral vaccine vector comprising an adenoviral genome with a deletion in the E1 region, and an insert in the E1 region, wherein the insert comprises an expression cassette comprising:

- i) a polynucleotide encoding a codon-optimized HPV16 protein selected from the group consisting of L1, E1, E2, and E7 proteins [or mutant forms thereof], wherein said polynucleotide is codon-optimized for expression in a human host cell; and
- ii) a promoter operably linked to the polynucleotide.

[29. A method according to Claim 28 wherein the vertebrate is human.]

30. (Twice Amended) A method of making a codon-optimized HPV16 protein comprising expressing in a human host cell a synthetic polynucleotide encoding a human papillomavirus serotype 16 (HPV16) protein, [or mutated form thereof which has reduced protein function for viral replication and cellular transformation as compared to wild-type protein, but which maintains immunogenicity,] wherein said polynucleotide sequence comprises codons optimized for expression in a human host.